Point-of-care Cardiac Publication Compendium
This compendium was compiled to provide one resource for journal publications for the Stratus® CS Acute Care™ Diagnostic System and its current commercial assays. Articles that contain claims or cite performance outside of the Information or Use instructions for the Stratus CS analyzer and associated assays have not been included.

These articles were published in various journals from the year 2003 through present and are provided for informational use only.
## Guideline Acceptable Sensitive Troponin I

### Analytical Performance

<table>
<thead>
<tr>
<th>Title of Publication</th>
<th>Systems/Assays Cited</th>
<th>Overview/Conclusions</th>
<th>Author</th>
<th>Journal</th>
<th>Year Published</th>
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</table>
| Clinical implications of the change of cardiac troponin I levels in patients with acute chest pain—An evaluation with respect to the Universal Definition of Myocardial Infarction. | • Stratus CS Acute Care Diagnostic System  
• Troponin I assay | This study sought to evaluate the clinical implications of the relative change of cardiac troponin I (cTnI) levels, and found that a peak cTnI level above the 99th percentile together with a cTnI change of ≥20% within 24 hours of admission led to a significantly raised mortality over the study period of 5.8 years. This study concluded that the universal definition of AMI together with a ≥20% cTnI change appears to improve the discrimination of acute from chronic causes of cTnI release, and allows a reliable identification of patients at risk. | Eggers KM, et al. | Clin Chim Acta. 412(1-2):91-7. | 2011 |
| Integration between point-of-care cardiac markers in an emergency/cardiology department and the central laboratory: methodological and preliminary clinical evaluation. | • Stratus CS Acute Care Diagnostic System  
• Troponin I assay | The analytical performance of the troponin I assay on the Stratus CS system was evaluated to assess the viability of implementation of POC testing. The preliminary clinical data suggest that the high sensitivity of the Stratus CS Troponin method could play an important role in early identification of patients with acute myocardial infarction. The comparison studies suggest that implementation of POCT requires a high level of integration between cardiologists and pathologists to guarantee appropriate interpretation of the monitoring results for suspected ACS patients. | Di Serio F, et al. | Clin Chem Lab Med. 43(2):202-9. | 2005 |
| Evaluation of imprecision for cardiac troponin assays at low-range concentrations.* | • Stratus CS Acute Care Diagnostic System  
• Abbott AxSYM  
• Bayer ACS:180  
• ADVIA Centaur® system  
• Bayer Immuno 1  
• Beckman Access  
• bioMerieux VIDAS  
• Byk-Sangtec Diagnostica Liaison  
• Dimension® RxL system  
• IMMULITE® One  
• Behring Opus  
• Ortho VITROS ECI  
• Roche Elecsys  
• Roche E170  
• Tosoh A1A 21  
• Troponin I assay | Imprecision profiles for commercially available cardiac troponin assays were constructed using AxSYM, ACS:180, ADVIA Centaur system, Immuno 1, Access, VIDAS, Liaison, Dimension, Opus, Stratus CS system, IMMULITE, VITROS ECI, and Elecsys analyzers. No assay was able to achieve the 10% CV recommendation at the 99th percentile reference limit defined by the manufacturer. | Panteghini M, et al. | Clin Chem. 50:327-32. | 2004 |
| Evaluation of point-of-care test systems using the new definition of myocardial infarction. | • Stratus CS Acute Care Diagnostic System  
• Troponin I assay  
• CK-MB assay | This study evaluated the clinical utility of the Stratus CS Troponin I test. Sensitivity and specificity were 100% and 95.3%, respectively, when 0.2 μg/L was used as the cutoff for myocardial infarction. Stratus CS Troponin I appeared to be a reliable method in the low-risk group studied. | Agewall S. | Clin Biochem. 36(1):27-30. | 2003 |

*This study was funded partially or fully by Siemens.*
## Assay Comparison

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| Stratus CS system cardiac troponin I method: performance characteristics including imprecision at low concentrations. | • Stratus CS Acute Care Diagnostic System  
• Dimension RxL system  
• Troponin I assay | The performance of the Troponin I assay on the Stratus CS system was assessed using a Dimension RxL system for comparison. The assay in routine practice has performance characteristics appropriate for clinical use, including good correlation to a central laboratory cTnI method and imprecision of a high-sensitivity troponin method, with a CV of <10% at the 99th percentile of the reference population. | Christenson RH, et al. | Clin Biochem. 37(8):679-83. | 2004 |

* Analytical performance of the i-STAT cardiac troponin I assay. | • Stratus CS Acute Care Diagnostic System  
• Abbott i-STAT System  
• Troponin I assay | The analytical characteristics of the i-STAT cardiac troponin I assay were assessed using the Stratus CS Troponin I assay for comparison. Regression analysis for the i-STAT cTnI between whole-blood and plasma specimens and for whole blood between the i-STAT and Stratus CS cTnI assays demonstrated slopes of 1.06 and 0.89, respectively. | Apple FS, et al. | Clin Chim Acta. 345(1-2):123-7. | 2004 |

## Hospital Metrics

| Decreased patient charges following implementation of point-of-care cardiac troponin monitoring in acute coronary syndrome patients in a community hospital cardiology unit. | • Stratus CS Acute Care Diagnostic System  
• Dimension RxL system  
• Troponin I assay | This study assessed bedside cTnI testing on the Stratus CS system with respect to turnaround times, patient length of stay, financial matrices, and patient outcomes compared to central laboratory cTnI testing on a Dimension system. This study demonstrates the cost effectiveness and clinical effectiveness of implementation of POC whole-blood cTnI testing for assisting clinicians with diagnostic and risk assessment of ACS patients. | Apple FS, et al. | Clin Chim Acta. 370(1-2):191-5. | 2006 |

## Patient Subsets

| Gender differences in correlates of troponin assay in diagnosis of myocardial infarction. | • Stratus CS Acute Care Diagnostic System  
• Troponin I assay  
• CK-MB assay | This study assessed the accuracy and correlates of Siemens, cardiac Troponin I (cTnI) assay on the Stratus CS system in the diagnosis of non-ST-segment elevation MI to determine how the assay might vary by gender. The study did not observe a significant difference in the assay sensitivity or specificity by gender. | Shoaibi A, et al. | Transl Res. 154(5):250-6. Epub 2009 Aug 3. | 2009 |
| Point-of-care testing: false elevation of cardiac troponin I assayed in the emergency department. | • Stratus CS Acute Care Diagnostic System  
• Troponin I assay | High cTnI levels in an 18-year-old woman with no cardiac history were discordant with the clinical presentation and electrocardiography. Assay interference by heterophilic antibodies (HA) was suspected and subsequently confirmed using a heterophilic blocking tube, a device that contains a blocking reagent composed of specific binders that attach to HA. | Pernet P, et al. | Am JEmerg Med. 26(8):969-971. | 2008 |
| Positive cardiac troponin I and T and chest pain in a patient with iatrogenic hypothyroidism and no coronary artery disease. | • Stratus CS Acute Care Diagnostic System  
• Troponin I assay | A cTnI level above threshold (0.13 μg/L) was measured in a thyroidectomized patient who presented with acute chest pain. The study found that cardiac troponins may be elevated in severe hypothyroidism without coronary artery disease, due to diffuse myocardial injury. | Buschmann IR, et al. | Int J Cardiol. 115(2):e83-5. | 2007 |

*This study was funded partially or fully by Siemens.
### D-dimer

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| Dendrimers and their applications in immunoassays and clinical diagnostics | • Stratus CS Acute Care Diagnostic System  

### NT-proBNP

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| PATHFAST NT-proBNP (N-terminal-pro B type natriuretic peptide): a multicenter evaluation of a new point-of-care assay | • Stratus CS Acute Care Diagnostic System  
• PATHFAST Analyzer  
• NT-proBNP assay | A multicenter evaluation was performed to assess a new point-of-care testing PATHFAST NT-proBNP assay. The assay was evaluated against Siemens, NT-proBNP assay running on the Stratus CS system. Satisfactory analytical and clinical performance was observed. | Zaninotto M, et al. | Clin Chem Lab Med. 48n7: 1029-34. | 2010 |

The Stratus® CS 200 Acute Care™ Diagnostic System is not available for sale in the U.S. Product availability varies by country.
The Stratus CS analyzer for acute-care diagnostics provides quantitative cardiac assays for fast, cost-effective evaluation of patients presenting with suspected myocardial ischemia. Its menu, efficiency, and ease of use make it ideal for both point-of-care testing and laboratory applications.

- This list of publications was compiled using the online service PubMed. PubMed is a service of the U.S. National Library of Medicine that includes over 19 million citations from MEDLINE and other life science journals. The service can be found at www.ncbi.nlm.nih.gov/pubmed. The following search terms were used: Stratus CS Analyzer.
- This publication list is updated no more than once annually. Although every attempt is made to include all relevant publications, no guarantee is made as to the completeness of this list.
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- Siemens is not practicing medicine nor offering medical advice. Please consult appropriate professionals about any condition or course of treatment for which you seek information.
- Siemens does not provide reprints of these publications; reprint inquiries should be directed to the respective publishers.

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